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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 07/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/517,981	BEARCROFT ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,20-22,26,64,65 and 67-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,20-22,26,64,65 and 67-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☒ Interview Summary (PTO-413) Paper No(s). *23* .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Objections

Claim 70 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim depends from itself.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,9,10,20-22,26,64,67-70,73-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard et al. (WO 94/08912). Fig. 2 shows a particle with six extremities having the same shape, size and angles between extremities. The particle also possesses bilateral symmetry in at least one plane. It is noted on page 2, lines 6-25 that spherical shaped or circular cross-section objects are known and Sheppard disclosed circular cross-sectional particles have better densities. Thus, Sheppard

acknowledged an understanding of packing particles with a circular cross-section in an array. Sheppard illustrates in Figs. 5,6 an array of particles with tapered extremities extending from the base. Therefore, it can be said that Sheppard does disclose a particle or array of particles having extremities with circular cross-sections, see MPEP 2123 to support this reasoning because the reference is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Sheppard also discloses ceramics and polymers are used for the particles, page 19, lines 26-28. Sheppard additionally discloses that ceramics can be used in bone replacement and periodontal disease requiring tooth implants, page 32, lines 20,27. Ceramic and glass particles can be broadly interpreted as composites that enable bone ingrowth to occur, page 19, lines 26-29. The projections inherently provide for interstitial spaces.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,4,9,20,21,26,64,67,69,70,75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. (5676700). Fig. 1 shows a shaped particle **10** having a center portion **C** and at least four tapered extremities **12** projecting from the center portion. It can also be seen in Fig. 1 that the ends of the extremities show a

rounded cross-sectional configuration. Additionally, as seen in Figs. 1 and 2, the extremities are of the same shape, size and the angles between adjacent extremities in the particle are approximately equal. Black also discloses the particle is made of materials such as ceramic or bioactive glass, col. 4, lines 14-18. Black additionally discloses the shaped particle is used for repair of bone, i.e. in diseased bone, voids in bone, col. 1, lines 30-60. Fig. 4 illustrates an array of a plurality of shaped particles. However, Black does not disclose the extremities have a circular cross-section. It would have been an obvious matter of design choice to modify the oval or rounded cross-section of Black and make it circular, since applicant has not disclosed that using a circular cross-section provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rounded cross-sectioned extremities of taught by Black et al. or the claimed circular cross-section in claim(s) 1, 26,75-77 because both perform the same function of providing for interstitial spaces between adjacent extremities and provide a porosity to allow for ingrowth.

Claims 5, 6,11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (WO 94/08912) in view of Chen et al. (6180606). Sheppard et al. is explained supra. However, Sheppard does not disclose the claimed materials for the particles or composite materials. Chen et al. teach that compositions used in periodontal repair are formed of calcium compounds, col. 2, lines 13-25. Polymers such as polylactic acid can be used for the matrix and composites can also be formed of polymer/ceramic or glass combinations, col. 3, lines 40, 41, 47-50, 60-65. It would have

been obvious to one of ordinary skill in the art at the time of the invention to substitute different ceramics and use calcium phosphate or combinations of materials such as polymer composites as taught by Chen for the particles of Sheppard et al. in order to enhance the osteogenic potential of the composition being used.

Claims 5-8,71,72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700 in view of Barralet (Biomaterials, 1993). Black is explained supra. However, Black does not disclose the ceramic as gypsum or the array to have a porosity between 40-80%. Barralet teaches that calcium sulfate or gypsum having a porosity of 60%, see Abstract. It would have been obvious to one of ordinary skill in the art to use calcium sulfate as taught by Barralet for the shaped particles of Black in order to provide a well accepted bone filler with a good porosity for bone ingrowth.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700 in view of Kondo et al. (JP 171546). Black is explained supra. However, Black does not disclose the particle diameter in the range of 6mm. Kondo et al. teach forming particles with protruberances or extremities on the surface having a diameter of 8mm, page 3, lines 9, 10. Kondo also teaches that the particles had excellent affinity for tissue, page 2, lines 9-11. It would have been obvious to one of ordinary skill in the art to use the teaching of Kondo to use diameters "about" 6 to 8mm for the particle of Black in order to encourage greater tissue ingrowth and improve the affinity for tissue growth.

Claims 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700. Black is explained supra. However, Black does not disclose resorbable

materials for the particles. It would have been an obvious matter of design choice to have a resorbable material for the shaped particle, since applicant has not disclosed that this material for the particle provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the ceramic or bioactive glass as taught by Black or the resorbable material of claim 65 because both materials are biocompatible and remain in the body of a sufficient time to permit bone ingrowth and provide the ability to fill the bone void.

Response to Arguments

Applicant's arguments filed 7/7/03 have been fully considered but they are not persuasive. A known or obvious particle does not become patentable simply because it has been described as somewhat inferior to some other product for the same use. In this instance and in response to the declaration of Mr. Cooper filed on 7/7/03, the arguments with respect to the Black patent are non-persuasive. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). It is also noted that Mr. Cooper states a difference in porosity exists between an oval and circular cross-section particle. However, this argument is irrelevant since a change in shape is obvious to one of ordinary skill in the art. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Thus forming a circular cross-section from an oval cross-section clearly would result in the claimed invention.

Regarding the comments about Sheppard in the response and declaration, it must be noted that Sheppard does not teach away from a shaped particle having circular cross-sectional extremities. Sheppard et al. improved upon interlocking capabilities, but disclosed and acknowledged the interstitial spaces in particles having circular cross-sectional configuration was not capable of achieving surface to surface contact for packing purposes which is important in filling a defect. As mentioned above in the rejection, MPEP 2123 states a reference may disclose an invention and its purpose of the a modification of what is known, but should also be considered for what can be understood in light of the entire document. In this case, Sheppard clearly mentions what can be considered a circular cross-section and discusses how a particle would interlock with other similar particles resulting aggregates with certain densities. Sheppard then pursued greater packing abilities by modifying a circular cross-section extremity by having planar sides such that there is more surface to surface contact for the extremities interlocking with adjacent particles in an array. Therefore, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-

5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
TC 3700, AU 3738